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09/936,173	01/18/2002	Gai-Li Jiao	2577-107	9552

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/936,173

Applicant(s)

JIAO ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 Janaury 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-30 are pending and are examined in the instant action.

### ***Information Disclosure Statement***

2. Applicant's IDS filed 4 March 2004 is acknowledged and a signed copy included herewith.

### ***Specification***

3. Claim 26 and 27 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should depend upon other claims in the alternative only. See MPEP § 608.01(n). In the interest of compact prosecution, the claim will be treated on the merits. Such treatment does not relieve Applicant of the responsibility to respond to this objection.

### ***Claim Rejections - 35 USC § 112-2***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1-30 rejected under 35 USC § 112-2 for the following reasons

In claim 1,

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- (a) "fibrous root explants" is unclear. Does "fibrous" refer to the root or to the explant? How does a fibrous root differ from a non-fibrous root?
- (c) "root callus" lacks antecedent basis.
- "gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, the language "a DNA of interest" is suggested. Or Applicant may recite the various components of the "gene" desired. All recitations of "gene" are also rejected.
- (e) "the selected callus culture" lacks antecedent basis.
- (f) "the induced somatic embryos" lacks antecedent basis.

In claim 2, "multiple effect triazole" does not name a chemical compound, rather this only says that the compound(s) have multiple effects. This is indefinite.

In claims 2-30, "about" is unclear, because the metes and bounds of "about" are not defined. All recitations of this usage are also rejected.

In claim 5 and 11, "the additional presence" is confusing; suggested language is "in the presence additionally of".

Corrections or clarifications are required.

***Claim Rejections - 35 USC § 112 Enablement***

6. Following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

*The breadth of the claims:* The claims are drawn to a method of producing a transgenic cotton plant comprising obtaining cotton fibrous root explants, culturing them to induce callus, exposing root callus to *Agrobacterium tumefaciens* comprising an exogenous gene and a selective marker gene, the *Agrobacterium* being capable of effecting a stable transfer of both genes to the callus cell genome, culturing the callus in the presence of selection agent, inducing somatic embryos in the selected callus and regenerating the induced somatic embryo into whole transgenic cotton plants. The claims are also drawn to pretreatment with multi-effect triazole, growth on medium comprising naphthalene acetic acid, myo-inositol, dimethylallyl(amino)purine, 2,4-D, MgCl<sub>2</sub>, glucose, gellan gum, and/or NaNO<sub>3</sub>.

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The claims are drawn broadly to all cotton, all culture media including any and all compositions, all Agrobacterium, all vectors, all exogenous genes, all selectable agents, and all selective markers. Applicant claims a method comprising the steps of (a) obtaining explants, (b) culturing them to induce callus, (c) exposing callus to Agrobacterium, (d) culturing this further with a selection agent, (e) inducing somatic embryo formation and (f) regenerating the somatic embryos into whole transgenic cotton plants.

*The state of the art and the unpredictability thereof.* Applicant acknowledges that (specification, page 10, 1<sup>st</sup> line) Agrobacterium mediated transformation of cotton is considered in the art to be heavily variety-dependent. According to Hansen, “[P]lant transformation is an art because of the unique culture conditions required for each crop species. To accommodate a genotype or species that has not been manipulated in culture previously, one must either adapt an established protocol or create a new one”, (Hansen et. al., 1999, Trends in plant Science, vol 4, pages 226-231, see page 230). A number of variable are known in the art which influence Agrobacterium mediated transformation and the regeneration of the tissue to whole plants: The specific stain of Agrobacterium used, the concentration of Agrobacterium used in cocultivation, the time and conditions of cocultivation, the plant tissue used in the cocultivation, the medium used and treatment conditions, including time duration, compositions, and concentration of reagents, for each step of the method. While the specification can provide clarification of elements which are known to one skilled in the art, *essential*

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*steps and conditions not known to one of ordinary skill in the art are unpredictable*, and must be recited in the claims. To define the specific stain of Agrobacterium used, the concentration of Agrobacterium used in cocultivation, the time and conditions of cocultivation, the plant tissue and explant used in the cocultivation, the medium used and treatment conditions, including time duration, compositions, and concentration of reagents, for each and all the steps of the method would requires a myriad of different combinations, subcombinations, and permutations of the variables. Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

*Working Examples:* Applicant teaches Agrobacterium mediated transformation of cotton as described in the specification (pages 10, line 22 through page 16, line 6).

In view of the breadth of the claims (all cotton plant, all culture media including any and all compositions, all Agrobacterium, all vectors, all exogenous genes, all selectable agents, and all selective markers), the nature of the invention, the unpredictability of the art, the lack of guidance in the specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Strickland (WO 97/12512 published 10 April 1997; US 5,846,797 issued 8 December 1998).

Strickland teaches a method of producing transgenic cotton comprising using explants of root tissue and root meristematic cells (page 11, lines 7-25 and page 12, line 12 bridging to page 13, line 4), on medium to induce callus formation (page 26, lines 5-13), coculturing with *Agrobacterium* (Abstract, and page 17, lines 1-15) containing a selectable marker gene (page 16, lines 9-27), culturing calli on selection medium (Table 4, page 26), induction of somatic embryos (p. 5, lines 12-14) and regeneration to whole transgenic plants (abstract).

Accordingly Strickland anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:



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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-4 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strickland (WO 97/12512 published 10 April 1997; US 5,846,797 issued 8 December 1998) as discussed above for claim 1, in view of Liang, et. al. Acta Agronomica Sinica, 1997, Vol 23, No. 2, pages 220-225, (IDS) and applicant's admitted prior art .

Strickland does not teach use of a multi effect triazole.

Liang, et. al teach the use of multi-effect triazole to promoter rooting in wheat. Applicant's admitted prior art (specification page 6, lines 24-31) acknowledges use of multi-effect triazole as a known chemical in agriculture used to promote root growth. One of ordinary skill in the art would have been motivated to use multi-effect triazole, as this appears to be a standard protocol.

Applicant's admitted state of the prior art teaches that the transformation and regeneration of cotton from wide variety of explants was known (specification page 1, lines 16-bridging to page 2, line 33).

Given the recognition of one of ordinary skill in the art of the value of a method of Agrobacterium mediated transformation of cotton, a known agronomically important crop, that functions with various explants including roots, as taught by Strickland, the fact that multi-effect triazoles are known to promote rooting as taught by Liang, et. al., one of ordinary skill in the art would have been motivated to combine the use of multi-

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effect triazole with the teachings of Strickland, to transform cotton, with a reasonable expectation of success. Accordingly the claimed invention is prima facie obvious in view of the prior art.

12. Claims 1 and 14-30 are rejected over Strickland (WO 97/12512 published 10 April 1997; US 5,846,797 issued 8 December 1998) as discussed above for claim 1, in view of Firoozabady et al., Plant Molecular Biology, vol. 10, pages 105-116, 1987 (IDS).

Strickland does not teach use of dimethylallyl(amino)purine.

Firoozabady et al teaches (table 1, page 21) use of MS medium identical to Applicant's CB-2-1 medium. This contains naphthalene acetic acid (0.1 mg/l , myo-inositol (100 mg/ml) , dimethylallyl(amino)purine, 2,4-D, MgCl<sub>2</sub>, glucose, gellan gum, and/or NaNO<sub>3</sub>.

Given the recognition of one of ordinary skill in the art of the value of a method of Agrobacterium mediated transformation of cotton, a known agronomically important crop, that functions with various explants including roots, as taught by Strickland, and the plethora of cotton tissue culture data as indicated by applicant's admitted prior art (specification page 1, lines 16-bridging to page 2, line 33), one of ordinary skill in the art would have been motivated to combine the use of dimethylallyl(amino)purine as taught by Firoozabady et. al. with the teachings of Strickland, to improve the cotton transformation, with a reasonable expectation of success. Accordingly the claimed invention is prima facie obvious in view of the prior art.

13. Claims 1-30 are rejected over Strickland (WO 97/12512 published 10 April 1997; US 5,846,797 issued 8 December 1998) as discussed above for claim 1, in view of Firoozabady et al., Plant Molecular Biology, vol. 10, pages 105-116, 1987 as discussed above for claims 1 and 14-30, and further in view of Liang, et. al. Acta Agronomica Sinica, 1997, Vol 23, No. 2, pages 220-225, (IDS) and applicant's admitted prior art, as discussed for claims 1-4 and 8-10.

Strickland does not teach the use of a multi-effect triazole and naphthalene acetic acid.

Firoozabady et. al. teach the use of naphthalene acetic acid, as stated above.

Liang et. al. teaches the use of multi-effect triazole.

Applicant's admitted state of the prior art teaches that the transformation and regeneration of cotton from wide variety of explants was known (specification page 1, lines 16-bridging to page 2, line 33).

One of ordinary skill in the art recognized the value of a method of Agrobacterium mediated transformation of cotton, a known agronomically important crop, that functions with various explants including roots, as taught by Strickland, the fact that multi-effect triazoles are known to promote rooting as taught by Liang, and the plethora of cotton tissue culture data as indicated by applicant's admitted prior art (specification page 1, lines 16-bridging to page 2, line 33). In addition, one of ordinary skill in the art would have been motivated to combine the use of dimethylallyl(amino)purine as taught by Firoozabady et. al. with the teachings of Strickland and Liang et. al., to improve cotton

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transformation, with a reasonable expectation of success. Accordingly the claimed invention is prima facie obvious in view of the prior art.

**Remarks**

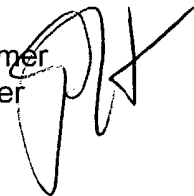
14. No claims are allowed.

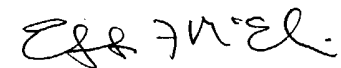
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer  
Patent Examiner  
Art Unit 1638  
May 4, 2004



  
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